WO 2004/039352 PCT/IB2003/004873

WE CLAIM:

- 1 1. An amorphous form of losartan potassium.
- 1 2. The amorphous form of losartan potassium of claim 1, wherein the losartan
- 2 potassium has the infrared spectrum of Figure 1.
- 1 3. The amorphous form of losartan potassium of claim 1, wherein the losartan
- 2 potassium has the X-ray diffraction pattern of Figure 2.
- 1 4. A pharmaceutical composition comprising:
- 2 a therapeutically effective amount of an amorphous form of losartan potassium;
- 3 and one or more pharmaceutically acceptable carriers, excipients or diluents.
- 1 5. The pharmaceutical composition of claim 1, wherein the losartan potassium has the
- 2 infrared spectrum of Figure 1.
- 1 6. The pharmaceutical composition of claim 1, wherein the losartan potassium has the
- 2 X-ray diffraction pattern of Figure 2.
- 1 7. A process for the preparation of the amorphous form of losartan potassium, the
- 2 process comprising:
- 3 preparing a solution of losartan potassium in one or more solvents; and
- 4 recovering the losartan potassium in the amorphous form from the solution thereof by the
- 5 removal of the solvent.
- 1 8. The process of claim 7, wherein the solvent comprises one or more of lower
- 2 alkanol, ketone, chlorinated solvent, water, or mixtures thereof.
- 1 9. The process of claim 8, wherein the lower alkanol comprises one or more of
- 2 primary, secondary and tertiary alcohol having from one to six carbon atoms.
- 1 10. The process of claim 8, wherein the lower alkanol comprises one or more of
- 2 methanol, ethanol, denatured spirit, n-propanol, isopropanol, n-butanol, isobutanol, and t-
- 3 butanol.
- 1 11. The process of claim 8, wherein the lower alkanol comprises one or more of
- 2 methanol, ethanol, and denatured spirit.
- 1 12. The process of claim 8, wherein the ketone comprises one or more of acetone, 2-
- 2 butanone, and 4-methylpentan-2-one.

WO 2004/039352 PCT/IB2003/004873

1 13. The precess of claim 8, wherein the chlorinated solvent comprises one or more of

- 2 chloroform, dichloromethane, and dichloroethane.
- 1 14. The process of claim 7, wherein removing the solvent comprises one or more of
- 2 distillation, distillation under vacuum, evaporation, spray drying, freeze drying, filtration,
- 3 decantation, and centrifugation.
- 1 15. The process of claim 7, wherein the losartan potassium in an amorphous form is
- 2 recovered from the solution by spray drying.
- 1 16. The process of claim 7, wherein the losartan potassium in an amorphous form is
- 2 recovered from the solution by freeze-drying.
- 1 17. The process of claim 7, wherein the losartan potassium in an amorphous form is
- 2 recovered from the solution by filtration.
- 1 18. The process of claim 7, further comprising additional drying of the product
- 2 obtained.
- 1 19. The process of claim 7, further comprising forming the product obtained into a
- 2 finished dosage form.
- 1 20. The process of claim 7, wherein the losartan potassium has the infrared spectrum
- 2 of Figure 1.
- 1 21. The process of claim 7, wherein the losartan potassium has the X-ray diffraction
- 2 pattern of Figure 2.